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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,939	03/16/2001	Mary Capelli-Schellpfeffer	3066.1000-001	7242

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,939

Applicant(s)

CAPELLI-SCHELLPFEFFER,
MARY

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80,82,87,89,92,93,101-103 and 107-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80,82,87,89,92,93,101-103 and 107-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's request for extension of time and amendment, both filed 02/18/2005.

Claims 81, 83-86, 88, 90, 91, 94-100, and 104-106 have been cancelled. Claims 109 and 110 have been added.

Claims 80, 82, 87, 89, 92, 93 101-103 and 107-110 are pending and included in the prosecution.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
2. The use of the trademark "AVOGEL" has been noted in this application. It should be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant has not responded to the above objections to the specification, therefore are maintained for reasons of record.

The following new grounds of rejections are necessitated by applicant's amendment:

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 80, 82, 87, 89, 92, 93, 101-103, and 107-110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not disclose "reducing the size of a closed wound" as currently recited in the amended claims. The specification discloses improving the size and appearance of the scar, page 6, lines 9-10, and improving the size can be either reduction of the size of elevated areas of the scar and elevation of the depressed parts of the scar. Therefore, no disclosure for reducing the size of the scar.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 80, 89, 92, 109 and 110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing because the generic claims 80 recites administering to the closed wound (which can be by injection or topical), while the dependent claims 89, 92 and 109-110 recite the composition comprising thermal insulating materials consisting of gel, hydrogel or sponge that are used only for topical formulations and not for parenteral formulations. On page 15, lines 1-3 of the present specification applicant discloses that the thermal insulating materials are placed in contact with the skin, i.e. topical application to the skin and not other routes of administration as injection.

Clarification is requested.

Claim 82 fails to further limit the subject matter of a previous claim 80 because claim 80 recites specific closed wounds caused by limited causes as indicated by the closed claim language "selected from group consisting of", and claim 82 is broadening the scope of claim 80 by adding more types of closed wounds such as those caused by surgery or reactive scar, etc.

Claim Rejections - 35 USC § 102

7. Claims 80 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08-268886 ('886).

JP '886 disclosed treatment and improvement of the skin diseases such as keloids by administering composition comprising aspirin or its salts in a carrier by

external application, orally or by injection (abstract; paragraphs 001, 0013, 0014, 0017, 0021).

Response to Arguments

8. Applicant's arguments filed 02/18/2005 have been fully considered but they are not persuasive. Applicant traverse this rejection by arguing that the reference does not teach reducing the size or improving the appearance of closed wound by NSAID, instead the reference teaches improving skin diseases by using composition comprising sagitrel and aspirin, wherein aspirin used to prevent clotting and reduces fever in the subject.

In response to these arguments, the examiner position is that the reference disclosed clearly improving the keloid, i.e. scar, and applicant admits the equivalency between the scar and the closed wound, page 6, lines 18-20 of the present specification. The other functions of aspirin to reduce fever or to prevent clotting are disclosed along with improving keloid and those functions are inherent for aspirin either used by applicant or by the prior art. The expression comprising of the claim language permits the presence of other ingredient such as sagitrel, regardless if the other ingredient is active or inactive and even if present in major amounts. The disclosure of the reference reads on the instant claims.

9. Claims 80, 82, 87, 93 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,521,271 ('271) with the effective filing date of August 16, 1999.

US '271 disclosed method of improving skin conditions such as scar by topical, oral or parenteral administration of a composition comprising 1-20% of salicylic acid and a carrier; and another antimicrobial agent or anti-inflammatory agent (abstract; col.3, lines 13-15, 35-37, 39-40; col.7, lines 15-23, 40; col.8, lines 19-21, 26, 30, 38-50).

Response to Arguments

10. Applicant's arguments filed 02/18/2005 have been fully considered but they are not persuasive. Applicant traverses the above rejection by arguing that the reference does not teach reducing the size or improving the appearance of closed wound by NSAID, instead teaches the salicylic acid as exfoliant.

In response to these arguments, the examiner position is that the reference clearly disclosed composition comprising salicylic acid treats scar, and applicant admits the equivalency between the scar and the closed wound, page 6, lines 18-20 of the present specification. The other functions of salicylic acid as enhancer is disclosed along with treating scar and this functions is inherent for aspirin either used by applicant or by the prior art. The expression comprising of the claim language permits the presence of other ingredient, active or inactive even in major amounts. The disclosure of the reference reads on the instant claims.

Claim Rejections - 35 USC § 103

11. Claims 103,107, and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 27 07 537 ('537).

DE '537 teaches formulations for treatment of keloids comprising salicylic acid in an amount of 1-3%. The formulation comprises gel and a substance that relieve skin irritation.

The reference however does not teach the hydrogel as the thermal insulating material, the amount of the non steroidal or the specific other active agent in the composition.

The art recognized the use of gel and anti-irritants in the composition comprising COX that is used to treat keloids, thus, the specific hydrogel material and the specific anti-irritants used by present invention do not impart patentability to the claims, absent evidence to the contrary. The amounts used by the present invention do not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition disclosed by DE '537 and select the specific thermal insulating materials and anti-irritants according to specific patient's need, and adjust the amounts according to the size and thickness of the scar, with reasonable expectation of having a composition comprising non-steroidal anti-inflammatory agent, anti-irritant, and a hydrogel that treat keloids with success.

Response to Arguments

12. Applicant's arguments filed 02/18/2005 have been fully considered but they are not persuasive. Applicant traverses the above rejection by arguing that the reference does not teach reducing the size or improving the appearance of closed wound by NSAID, instead treating acne that is infected and needs drainage.

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In response to the above applicant's argument, the examiner position is the rejected claims are directed to composition, and all the elements of the composition are disclosed by the reference, and the intended use of the composition does not impart patentability to composition claims. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

13. Claims 87, 89, 92, 93 101-103 and 107-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '886 in view of US 5,552,162 ('162).

The teachings of JP '886 are discussed above. JP '886 does not teach the thermal insulating material, the amount of the non-steroidals or the other active agents in the composition.

US '162 teaches a method for improving the size and appearance of the scar associated with keloid or hypertrophic wound healing disorder by covering the scar with thermal insulating material and active agent (abstract). The thermal insulating materials includes hydrogel and gel (col.9, lines 10-12, 27). The thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar (col.6, lines 1-32).

The specific other active ingredients used by present invention do not impart patentability to the claims, absent evidence to the contrary. The amounts used by the present invention are within skill in the art to determine, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the keloid by administering a composition comprising aspirin as disclosed by JP '886, and add thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar of the closed wound with success.

14. Claims 89, 92, 93 101-103 and 107-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '271 in view of US '162.

The teachings of the references are discussed above. US '271 does not teach the hydrogel as the thermal insulating material, or the specific other active agent in the composition.

The specific other actives used by present invention do not impart patentability to the claims and it is within the skill in the art to add any other additives or actives as needed, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the scar by administering a composition comprising non-steroidal anti-inflammatory agent as disclosed by US '271, and add the thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar of the closed wound with success.

Response to Arguments

15. Applicant's arguments filed 12/18/2005 have been fully considered but they are not persuasive. Applicant traverses the obviousness rejection of the claims over JP '886 and US '271 in view of US '162 by arguing that US '162 neither discloses nor suggests using aspirin to achieve improvement in the size or appearance of a closed wound.

In response to this argument the examiner position is US '162 is relied upon for the solely teaching of thermal insulating material combined with medicaments to reduce the size of the scar, as desired by applicants. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800

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F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

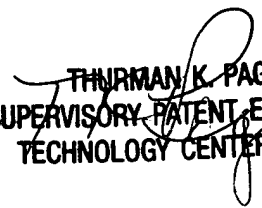
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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